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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,343	11/01/2005	Akira Kato	1089.0590000/MAC	4524

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
02/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/555,343	KATO ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 January 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *28-43*.
   Claim(s) withdrawn from consideration: *16-18 and 21-23*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628

/CRAIG RICCI/
Examiner, Art Unit 1628

Continuation of 11. does NOT place the application in condition for allowance because: As argued by Applicant, the invention of Miyake requires the ingredient of a polyhydric alcohol to overcome problems with prior inventions and is thus a necessary element in Miyake's preparations (Applicant Argument, Page 10). Applicant contends that the instant claims, which do not specifically recite the inclusion of polyhydric alcohols, are thus not obvious and that "it is not necessary... to exclude unrelated components, such as polyhydric alcohols, which are only an option in the claimed compositions in order to establish the non-obviousness of the claimed invention". Applicant's argument is not persuasive. The prima facie obvious invention would comprise the polyhydric alcohols. Applicant's claimed invention, using comprising language, includes the prima facie obvious invention having said polyhydric alcohols. Applicant nexxt argues that it would not have been obvious to substitute cyanocobalamin with methylcobalamin (Applicant Arguments, Page 14). In particular, Applicant argues it would not be "obvious to try" said substitution (applicant Arguments, Page 14). Applicant's arguments are not persuasive. First, it is noted that no where was the motivation to substitute the cobalamins based on an "obvious to try" rationale. As such, this argument is not consdered pertinent. Second, as discussed in the previous Action, methylcobalamin is the active form of vitamin B12 (as evidenced by Driskell (Page 75)). Accordingly, as discussed in the previous Action, the ordinarily skilled artisan would have found it prima facie obvious to replace cyanocobalamin in the formulation taught by Miyake et al with methylcobalamin in view of Diskell. The skilled artisan would have been motivated to formulate the vitamin preparation comprising vitamin B12 taught by Miyake et al using methylcobalamin in view of Diskell, who teaches that methylcobalamin (not cyanocobalamin) is the active form of vitamin B12. Applicant lastly argues that there is no disclosure that the lactose in the prima facie obvious invention based on the prior art would be in an amorphous form (Applicant Arguments, Pages 14-15). Yet, as previously discussed, although Miyake et al do not specifically disclose that the lactose in the freeze-dried preparation is amorphous or that the methylcobalamin in the freeze-dried preparation is amorphous, it is asserted – absent evidence to the contrary – that the lactose and methylcobalamin would necessarily be in an amorphous state in the freeze-dried preparation taught by Miyake et al in view of Driskell. As stated in In re Best, Bolton, and Shaw, "Where... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product" 195 USPQ 430, 433, 562 F2d 1252 (CCPA 1977). In the instant case, the claimed and prior art products are substantially identical. Accordingly, it is asserted that the prior art freeze-dried product would necessarily comprising amorphous lactose and amorphous methylcobalamin, absent evidence to the contrary. See also In re Fitzgerald 205 USPQ 594, 597, 619 F2d 67 (CCPA 1980): the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on. Since Applicant has not introduced any evidence to suggest otherwise, the argument is not found persuasive.